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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,994	10/21/2003	Edgar B. Cahoon	BB1295USCNT	1315
23906 7590 08/08/2007 E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE WILMINGTON, DE 19805			EXAMINER ZHENG, LI	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 08/08/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/690,994	<b>Applicant(s)</b> CAHOON ET AL.	
	<b>Examiner</b> Li Zheng	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 29-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's cancellation of claims 27-28, amendments to claim 26, as well as submission of declaration under 37 C.F.R. § 1.132 filed on 5/22/2007 are acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. All the rejections of claims 27-28 are withdrawn due to claim cancellation.

### ***Claim Rejections - 35 USC § 101***

4. Claims 26 and 29-40 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well-established utility, for the reasons of record stated in the Office action mailed December 18, 2006. Applicants traverse in the paper filed May 22, 2007. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the claims as currently amended are drawn to a polypeptide with diacylglycerol acyltransferase (DGAT) activity and at least 90% identity to SEQ ID NO: 16; that the specification describes amino acid sequence homology of SEQ ID NO: 16 with known and putative DGAT protein; and that the specification note on page 29 that assays for DGAT activity are presented by Andersson et al. (response, page 4, 5<sup>th</sup> paragraph). However, such amendment and arguments do not overcome the rejection under 35 U.S.C. 101, as the function of SEQ ID NO: 16 is assigned only base on limited sequence homology to other known or putative DGAT proteins.

Applicants further argue that the newly submitted declaration by Dr. Roesier demonstrated that a soybean protein with only one residue differing from SEQ ID NO: 16 shows DGAT activity, together with a putative wheat DGAT (response, page 4, the 2<sup>nd</sup> paragraph from the bottom of the page). However, The experiment conducted to obtained to result shown in declaration is not fully described in the specification, therefore the data can not be used to supported the utility of SEQ ID NO: 16.

### ***Claim Rejections - 35 USC § 112***

5. Claims 26 and 29-40 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

Art Unit: 1638

was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed December 18, 2006. Applicants traverse in the paper filed May 22, 2007. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that there are several known diacylglycerol acyltransferase (DGAT) polypeptides at the time of the invention and several others in references published subsequently (response, page 5, the 3<sup>rd</sup> paragraph). However, the reference published post the time of the instant invention can not be used to demonstrate that Applicants have the possession of the claimed sequences at the time of the invention. Further, as stated in previous office action, neither the specification nor the prior art discloses any polypeptide that is at least 90% identical to SEQ ID NO: 16 except for SEQ ID NO: 16 itself. Applicants failed to describe representative number of species in the claimed genus.

Applicants further argue that those disclosed sequences represent a description of structural characteristics common to DGAT polypeptides and demonstrate possession of the claimed sequences (response, page 6, the last paragraph to page 7, the 1<sup>st</sup> paragraph). However, the motifs of obtained by alignment of DGAT genes, respectively. Applicants specifically pointed out a candidate diacylglycerol-binding domain presented in Figure 7A of Oelkers et al and a consensus sequence of domain B (response, page 6, 3<sup>rd</sup> paragraph). However, there is no experimental evidence shown by either the specification or prior art that the motif is essential and sufficient for the DGAT function. What else besides this motifs might constitute essential structures for

Art Unit: 1638

DGAT activity? Thus, the specification does not describe conserved structures of SEQ ID NO: 16 that are essential to its functional activity. Without correlating the conserved structure to the function, even if it is known in the art that conservative amino acid substitutions can be made (response, page 12, 3<sup>rd</sup> paragraph), a person skilled in the art still would not know which residues can be modified and to which residue such substitution can be made.

In conclusion, the specification does not provide enough description for nucleotide sequences encoding polypeptides that are at least 90% or 95% identical to SEQ ID NO: 16.

6. Claims 26 and 29-40 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the biological function of SEQ ID NO:16 was known and enable, polypeptides that are at least 90%/95% identical to SEQ ID NO:16 would still not be enabled. The rejection is maintained for the reasons of record stated in the Office action mailed December 18, 2006. Applicants traverse in the paper filed May 22, 2007. Applicants' arguments have been fully considered but were not found persuasive.

Applicants submit that for reasons cited above regarding the rejection under 35 U.S.C. 101, there is a specific and substantial utility for the claimed invention.

However, the enablement rejection remains because the rejection under 35 U.S.C. 101 is maintained by the Office for the reason as discussed above.

Applicants argue that the claims as currently amended are drawn to a polypeptide with diacylglycerol acyltransferase (DGAT) activity and at least 90% identity to SEQ ID NO: 16; that the specification describes amino acid sequence homology of SEQ ID NO: 16 with known and putative DGAT protein; and that SEQ ID NO: 16 has the conserved domains A and B and conserved residues Ser-210 and Pro-224. However, the conserved domains A and B themselves are putative motifs that need to be proved experimentally. What else besides those motifs might constitute essential structures for DGAT activity? Thus, the specification does not describe conserved structures of SEQ ID NO: 16 that are essential and sufficient to its functional activity. Without correlating the conserved structure to the function, even if it is known in the art that conservative amino acid substitutions can be made (response, page 8, 2<sup>nd</sup> paragraph), a person skilled in the art still would not know which residues can be modified and to which residue such substitution can be made. Therefore, without further guidance, to generate claimed genus of sequences is undue. For example, the sequence of SEQ ID NO: 16 consists of 504 residues. A polypeptide having 90% identity to it differs in any 50 residues. One skilled in the art would not just randomly change any 50 residues of SEQ ID NO: 16, by any type of addition, substitution, and/or deletion, to obtain a sequence that differs by 10%. One requires further guidance regarding the regions of SEQ ID NO: 16 that can tolerate change, and one requires guidance regarding the type of change that would be. Furthermore, as discussed in

Art Unit: 1638

previous office action, Lazar et al. and Hill et al teach that making "conservative" substitutions (e.g., substituting one polar amino acid for another, or one acidic one for another) does not produce predictable results (previous office action, page 9, 2<sup>nd</sup> paragraph). Guo et al. teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (previous office action, page 9, 3<sup>rd</sup> paragraph).

### ***Summary***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

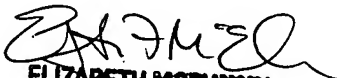


Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ELIZABETH MCELHANN  
PRIMARY EXAMINER